

Section 5. 510(k) Summary

K130415

1 Administrative

MAR 26 2013

Device Information

Device Name: High Metabolite QUALICHECK
Common Name: Quality Control
Product Code: JJS
Registration Number: 21 CFR 862.1660
Classification: Class I
Classification Panel: Clinical Chemistry

Submitter

Company Name: Radiometer Medical ApS
ER Number: 3002807968
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2 Description of Device

High Metabolite QUALICHECK is a single level quality control system consisting of:

- High Metabolite QUALICHECK (S7570)

The system consists of 30 ampoules per box. One ampoule contains 2 mL of solution.

The quality control solution is an aqueous solution containing a biological buffer, salts, metabolites, and a preservative.

3 Intended Use

This High Metabolite QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.

Analytes are: pO_2 , ctHb, cGlucose, cLactate

4 Substantial Equivalence

The High Metabolite QUALICHECK is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacturer:

K980135 QUALICHECK5+, Radiometer Medical ApS

Similarities		
Issue	SE Device	Predicate: QUALICHECK5+ (K980135)
Form	Same	Liquid
Base matrix	Same	Aqueous solution
Blood Gas Measurement	Same	pO ₂
Oximetry Measurement	Same	ctHb
Metabolite Measurement	Same	cGlucose, cLactate
Compatible analyzers	Same	<ul style="list-style-type: none">• ABL520• ABL555• ABL600/605/610/615/620/625• ABL700/705/710/715/720/725/730/735• ABL805/810/815/820/825/830/835/ BASIC• EML105

Differences		
Issue	SE Device	Predicate: QUALICHECK5+ (K980135)
Intended Use	<p>This High Metabolite QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.</p> <p>Analytes are: pO_2, ctHb, cGlucose, cLactate</p>	For In Vitro Diagnostic Use. This QUALICHECK5+ solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges. For professional use.
Storage	2 °C to 8 °C until expiration date.	2 °C to 25 °C until expiration date, including up to a total of 15 days at up to 32 °C
Open Vial Claim	High Metabolite QUALICHECK solutions are light and heat sensitive. Avoid storage in direct sunlight. Use immediately after opening the ampoule	Ampoules should be conditioned for at least five hours at a constant temperature between 18 °C and 32 °C before use. To maintain the reliability of the blood gas parameters, you must use the contents of the ampoule immediately after opening and according to the instructions in the operator's manual for the relevant analyzer.
Preservatives	Germall II, Kathon	ProClin 950
Blood Gas Measurement	pH, pCO_2 not included	pH, pO_2 , pCO_2 in all four levels
Oximetry Measurement	sO_2 , FO_2Hb , $FCOHb$, $FMethb$, $FHbf$ not included	sO_2 , FO_2Hb , $FCOHb$, $FMethb$, $FHbf$ in all four levels
Electrolyte Measurement	Electrolyte Measurement not included	cK^+ , cNa^+ , cCa^{2+} , cCl^-
Hemoglobin Measurement	Hemoglobin Measurement not included	ctBil
Levels	One level	Four levels
Target ranges	Target ranges, see Section 12.02 Target values	Target ranges, see Section 12.02 Target values
Compatible analyzers	<ul style="list-style-type: none"> • ABL800 • ABL817/827/837 • ABL77 	<ul style="list-style-type: none"> • ABL5 • ABL500/510 • ABL505 • ABL80 - CO-OX SW • ABL80 - OSM SW

Differences		
Issue	SE Device	Predicate: QUALICHECK5+ (K980135)
		<ul style="list-style-type: none">• ABL90 Flex

5. Stability

Stability studies and claims are based on real time stability study. Control solutions are stable for 2 years at 2-8 degrees C.

In-use Stability: The contents should be used immediately after opening.

6. Value Assignment

To determine the assigned values and control ranges for the High Metabolite QUALICHECK, six (6) trays of 1000 ampoules are sampled randomly from the Range+ QUALICHECK batch.

Twelve ampoules are sampled from each of the trays and 72 ampoules are sampled from the reference batch. The samples are conditioned and shaken at 25°C in a water bath for 6 hours. Measurements are performed on a minimum of 3 validated ABL7xx series devices with data collection. Measurement of each parameter is performed alternately on the reference ampoule and the sample ampoule and repeated 12 times on each ABL7xx for a total of 144 measurements. Target ranges are calculated based on the mean $\pm 2SD$.

7. Conclusion

The High Metabolite QUALICHECK is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate device: QUALICHECK5+ (K980135).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 26, 2013

Radiometer Medical Aps
c/o Martin Gabler
Aakandevej 21, Broenshoej
DENMARK DK-2700

Re: k130415

Trade/Device Name: High Metabolite QUALICHECK
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJS
Dated: February 06, 2013
Received: February 19, 2013

Dear Mr. Gabler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.

Director

Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130415

Device Name: High Metabolite QUALICHECK

Indications for Use:

This High Metabolite QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.

Analytes are: pO₂, ctHb, cGlucose, cLactate

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130415